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10/521,596	06/09/2005	Yoichi Kawazu	2144.0300000/RWE/JKM	4564
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EXAMINER				
MEHTA, ASHWIN D				
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/521,596

**Applicant(s)**

KAWAZU ET AL.

**Examiner**

Ashwin Mehta

**Art Unit**

1638

**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 04 February 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-12, 17-19 and 21-43 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-3, 7-9 and 21 is/are allowed.
- 6) ☒ Claim(s) 4, 5, 11, 12, 18, 22, 23 and 25-43 is/are rejected.
- 7) ☒ Claim(s) 24 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 02042008
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

**DETAILED ACTION**

1. The amendments filed February 4, 2008 were entered.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
3. The objections to claims 4, 5, 9, and 11 are withdrawn in light of the claim amendments.
4. The rejection of claims 1-5 and 9 under 35 U.S.C. 101 is withdrawn, in light of the claim amendments.
5. The rejection of claims 15 and 20 under 35 U.S.C. 112, 2<sup>nd</sup> paragraph is moot, in light of their cancellations.
6. The rejection of claims 4, 5, 9, 12-16, 18, and 20 under 35 U.S.C. 112, 1<sup>st</sup> paragraph, lack of written description, is withdrawn upon further consideration.

***Claim Objections***

7. Claims 4, 5, 26, 30, 35, 39, and 40 are objected to because of the following informalities: the recitations, "15 nucleic acids" and "100 nucleic acids" should be amended to --15 nucleotides-- and --100 nucleotides--, respectively.

Claim 11 is objected to because of the following informality: in line 8, "SEA" should be -SEQ--. Appropriate correction is required.

8. Claim 24 is objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim cannot depend from another multiply dependent claim. See MPEP § 608.01(n). Accordingly, the claim has not been further treated on the merits.

***Claim Rejections - 35 USC § 112***

9. Claims 4, 5, 11, 12, 22, 23, 25-28, 30-32, 34-37, and 39-42 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 4, 5, 28, 32, 34, 37, 39, and 42: the recitation, "at least about" renders the claims indefinite. It is unclear what range is to be covered by this recitation. The metes and bounds of the claims are unclear.

Further in claims 4 and 5: the recitation, "encodes comprises" in line 1 of part (b) of both claims also renders the claims indefinite. It is unclear what is meant by this recitation.

In claim 11: the recitation, "vector comprising the nucleic acid of (a)" renders the claim indefinite. Part (a) is directed to culturing a transformed cell, and not to a nucleic acid.

In claim 25: the claim is indefinite because it is unclear if the propagation material comprises the nucleic acid, DNA, or vector. It is suggested that the claim be amended to by adding the following at the end: --, wherein said material comprises said nucleic acid, DNA, or vector--.

10. Claims 4, 5, 12, 22, 23, 25-32, 34-37, and 39-42 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are broadly drawn towards any isolated DNA encoding a sense RNA comprising at least 15 nucleic acids that is at least about 90% complementary to, and hybridizes with, a nucleic acid that is 100% complementary to an RNA encoding the coat protein of MiLV, comprising (a) a nucleic acid encoding SEQ ID NO: 2 or (b) the nucleic acid of comprising the coding region of SEQ ID NO: 1; or an isolated DNA encoding an antisense RNA comprising at least 15 nucleic acids that is at least about 90% complementary to, and hybridizes with, an RNA encoding the coat protein of MiLV, comprising (a) a nucleic acid encoding SEQ ID NO: 2 or (b) the nucleic acid of comprising the coding region of SEQ ID NO: 1; or wherein the sense or antisense RNA is at least about 95%

The specification on page 7 discusses DNAs encoding RNAs of the invention. Support is found for RNAs having complementarity of 90% or higher, or 95% or higher, to RNAs encoding MiLV proteins, or to RNAs complementary to the complementary strand of RNAs encoding SEQ ID NO: 2. However, written description support is lacking for nucleic acids that are "at least about" 90% or 95% complementary to the RNAs recited in claims 4 and 5. The recitation, "at least about" is NEW MATTER and must be removed from the claims. Support is also

lacking for the recitation, “at least 1000 nucleic acids”, recited in claims 27, 31, 36, and 41. This recitation is also NEW MATTER and must be removed from the claims.

11. Claims 4, 5, 12, and 18 remain and new claims 22-43 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated DNA encoding a sense RNA completely complementary to the completely complementary strand of bases 87-1400 of SEQ ID NO: 1, and an isolated DNA encoding an antisense RNA completely complementary to bases 87-1400 of SEQ ID NO: 1, does not reasonably provide enablement for other DNAs encompassed by claims 4 and 5. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims, for the reasons of record stated in the Office action mailed October 2, 2007. Applicants traverse in the papers filed February 4, 2008. Applicants’ arguments were fully considered but were not found persuasive.

Applicants argue that a person of ordinary skill in the art would have been able to produce numerous RNA molecules that were complementary to SEQ ID NO: 1, including sequences that were 90-100% complementary and at least 15 bases (response, page 17, 2<sup>nd</sup> full paragraph). In response to the issue that RNAs of less than 23 nucleotides in length do not act as silencers of targeted nucleic acids, Applicants disagree and note that present claims 4 and 5 do not require that the recited RNAs be capable of inhibiting expression of the target protein, that all that is required is that the RNA hybridize with the recited RNA molecules (response, page 18, 1<sup>st</sup> full paragraph). However, the inhibition of expression of the MiLV coat protein of SEQ ID NO: 2 is the only function for the claimed nucleic acids taught in the specification. The claims as

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written encompass isolated DNAs encoding RNAs that do not have this function. If the claimed nucleic acids cannot inhibit the expression of SEQ ID NO: 2, what other functions do they have? Claim 4 encompasses isolated DNA molecules encoding sense RNAs at least 15 nucleotides and is at least about 90% complementary to a nucleic acid that is 100% complementary to RNA that encodes the coat protein of MiLV of SEQ ID NO: 2 or to the coding region of SEQ ID NO: 1. As pointed out by Applicants, the claimed nucleic acid need only have the recited size and complementarity. Therefore, the claim encompasses DNAs encoding RNAs that do not function to cause the RNA silencing of SEQ ID NO: 2, or that do not encode SEQ ID NO: 2. The functions of such DNAs are not taught by the specification, and it is unclear how one skilled in the art is to use them. Claim 5 also encompasses isolated DNAs that do not function to post-transcriptionally suppress the expression of SEQ ID NO: 2. Other functions for such DNAs encompassed by the claim are also unknown. In the absence of further guidance, undue experimentation would be required by one skilled in the art to determine other functions for the claimed isolated DNAs, and transformed cells and plants comprising them. See *Genentech, Inc. v. Novo Nordisk, A/S*, 42 USPQ2d 1001, 1005 (Fed. Cir. 1997), which teaches that “the specification, not the knowledge of one skilled in the art” must supply the enabling aspects of the invention.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

12. Claims 4, 5, 28, 29, 32, 33, 34, 37-39, 42, and 43 are rejected under 35 U.S.C. 102(b) as being anticipated by New England Biolabs Catalog (1996/1997, page 111).

The claims are broadly drawn towards any isolated DNA encoding a sense RNA comprising at least 15 nucleic acids that is at least about 90% complementary to, and hybridizes with, a nucleic acid that is 100% complementary to an RNA encoding the coat protein of MiLV, comprising (a) a nucleic acid encoding SEQ ID NO: 2 or (b) the nucleic acid of comprising the coding region of SEQ ID NO: 1; or an isolated DNA encoding an antisense RNA comprising at least 15 nucleic acids that is at least about 90% complementary to, and hybridizes with, an RNA encoding the coat protein of MiLV, comprising (a) a nucleic acid encoding SEQ ID NO: 2 or (b) the nucleic acid of comprising the coding region of SEQ ID NO: 1; or wherein the sense or antisense RNA is at least about 95% or is 100% complementary.

The New England Biolabs catalog shows that random primers were available before the priority date of the instant application, comprising combinations of sequences, including those that are 24 or 36 nucleotides in length. This would encompass those that encode RNAs that are at least about 90% complementary to a nucleic acid that is 100% complementary to RNA encoding the coat protein of MiLV, comprising (a) a nucleic acid encoding SEQ ID NO: 2 or (b) the nucleic acid of comprising the coding region of SEQ ID NO: 1, and that encode RNAs that are at least about 90% complementary to, and hybridizes with, an RNA encoding the coat protein of MiLV, comprising (a) a nucleic acid encoding SEQ ID NO: 2 or (b) the nucleic acid of comprising the coding region of SEQ ID NO: 1. The property of hybridizing to the RNA recited in the claims is inherent to RNA encoded by the DNA taught in the reference.

***Summary***

13. Claim 24 is objected; claims 4, 5, 11, 12, 18, 22, 23, and 25-43 are rejected; claims 1-3, 7-9, and 21 are allowed; claims 13-16 and 20 are cancelled.

14. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

***Contact Information***

Any inquiry concerning this or earlier communications from the Examiner should be directed to Ashwin Mehta, whose telephone number is 571-272-0803. The Examiner can normally be reached from 8:00 A.M to 5:30 P.M. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Anne Marie Grunberg, can be reached at 571-272-0975. The fax phone numbers for the organization where this application or proceeding is assigned are 571-273-8300. Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The

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toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

April 24, 2008

/Ashwin Mehta/  
Primary Examiner, Art Unit 1638